



COUNTY OF LOS ANGELES

CHIEF INFORMATION OFFICE

500 WEST TEMPLE STREET
493 HALL OF ADMINISTRATION
LOS ANGELES, CALIFORNIA 90012

JON W. FULLINWIDER
CHIEF INFORMATION OFFICER

TELEPHONE: (213) 974-2008
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May 29, 2002

To: Supervisor Zev Yaroslavsky, Chairman
Supervisor Yvonne Brathwaite Burke, Chair Pro Tem
Supervisor Gloria Molina
Supervisor Don Knabe
Supervisor Michael D. Antonovich

From: Jon W. Fullinwider
Chief Information Officer

Subject: **HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT –
STATUS**

During your meeting of June 19, 2001, your Board directed the Chief Administrative Officer and the Chief Information Officer to report on Health Insurance Portability and Accountability Act of 1996 (HIPAA) initiatives undertaken by the County. This is the fourth report in response to that request. Attachment A is a matrix of HIPAA-related contract expenditures. Attachment B provides a summary of expenditures with the Internal Services Department (ISD) related to HIPAA. Attachment C is an overall summary of the County's HIPAA compliance efforts to date, including Transactions and Code Sets, Privacy, and Security.

Attachments D, E, F, and G are the work plans for the County's HIPAA compliance activity.

The most important recent HIPAA development is the posting of a Notice of Proposed Rule Making (NPRM) by the Department of Health and Human Services (HHS) on March 27, 2002, that proposes significant changes to the HIPAA Privacy rules. Lloyd W. Pellman, County Counsel, issued a memo on May 16, 2002 (Attachment H), that describes the content and implications of the NPRM.

Public comments on the NPRM were due to HHS by April 26, 2002. HHS is now reviewing the comments and is expected to deliver a final change to the Privacy rules by September 2002, just seven months before the HIPAA Privacy deadline of April 14, 2003.

The Los Angeles County HIPAA Compliance Task Force held a special session on May 1, 2002, to assess the impact of the Privacy NPRM and formulate recommendations to your

Board. The meeting included Task Force members, managers from involved departments, and Robyn Meinhardt of Foley and Lardner. Because the issues for several departments or programs were of such complexity that final recommendations could not be determined on May 1, several follow-up sessions have been scheduled or are being scheduled to develop recommendations by Jun 28, 2002. The department summaries in Attachment C provide a brief status of departments with regard to the NPRM.

Electronic Transactions and Code Sets

All of DHS and DMH and one program in the Department of Probation (Probation) are directly impacted by the Transactions and Code Sets regulations. Probation's Transaction-related issues are relatively minor since DMH actually executes just one HIPAA Transaction on Probation's behalf.

The current deadline for compliance with the Transactions and Code Sets rules of HIPAA is October 16, 2002, but the County can apply for an extension to October 16, 2003. In order to apply for an extension, the County must have a plan to achieve compliance by October 16, 2003, and begin testing of compliant transactions by April 16, 2003. The County must also have a budget for HIPAA compliance consistent with the plan. The County application will combine the information from DHS and DMH into a single application. DMH has a remediation plan and DHS is within weeks of finalizing theirs. The one transaction DMH performs for Probation is included in the DMH remediation plan. Once the County's budget is sufficiently defined to know the status of HIPAA funding for the two departments, the County can file its extension request. August 2002 is the target time frame for seeking Board authorization to submit the County's extension request. The County has until October 15, 2002, to file its request.

DMH has begun the process of contracting for delivery of a solution for its Transactions and Code Sets issues. The contractor will be responsible for delivering the technical solution, but DMH still has significant concerns about the number of resources available to work with the contractor on procedures, data mapping and other tasks necessary to achieve HIPAA compliance.

Comdisco, the DHS prime contractor for its HIPAA assessment, gap analysis, and remediation planning, has been sold, with the exception of the DHS contract. The DHS contract with Comdisco has been assigned to SecureSoft Systems, Inc. (SecureSoft) effective May 13, 2002. SecureSoft, in coordination with its subcontractor, Fox Systems, Inc., is working to complete the assessment, gap analysis, and remediation recommendations by June 2002. A slight delay was introduced because of the transition of the contract. DHS has reorganized management of its HIPAA project and I believe this will improve collaboration between DHS and my office regarding HIPAA issues.

The State of California has taken a preliminary position that DHS must submit itemized claims for reimbursement for patient services in order to comply with HIPAA. DHS currently bills for patient services on an all inclusive rate basis (all services and supplies included in a single charge per visit or inpatient day). DHS sent a letter to the State of California on March 7, 2002, taking a position that DHS shall continue its present practice of all-inclusive billing and comply with HIPAA. The State acknowledged the letter on May 25, 2002, and stated that they were reviewing it and did not have a response yet.

The Auditor-Controller (AC), Internal Services Department (ISD), and Treasurer and Tax Collector (TTC) do not perform any of the HIPAA transactions themselves, but they do assist and participate in the execution of some of these transactions with DHS and DMH. The precise impact of this involvement is still being assessed.

HHS reported that they are preparing a NPRM for changes to the Transactions and Code Set rules for June 2002.

National Identifiers

HIPAA rules for national identifiers for individuals, providers, and clearinghouses have not been finalized. The final identifier rules for employers have been announced for a June 2002 release and the proposed identifier rules for health plans have been announced for an August release. The national identifier for individuals is on hold indefinitely.

Privacy

The Privacy regulations compliance date remains April 14, 2003, less than a year away. A detailed report on the impact of the Privacy NPRM will follow, with recommendations to your Board, as soon as the follow-up assessment sessions are completed.

The Department of Human Resources (DHR) posted the bulletin for the County Information Privacy Officer (CIPO) on May 17, 2002. This is a very important step to achieving HIPAA compliance. DHS, DMH, and County Counsel are being asked to participate in the selection of the CIPO because of the scope of their privacy concerns and the fact that they will work with the CIPO.

As requested in a letter I sent to DHS, DMH, and the Sheriff recommending that they name a Departmental Privacy Officer or Privacy liaison, to function as a liaison to the CIPO, all three departments have identified someone for that role.

Security

The final rules for Security are not yet published, but HHS has announced they will be



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Security

The final rules for Security are not yet published, but HHS has announced they will be

ready for an August 2002 release.

While the HIPAA Security Rules are expected to apply to the same departments as the Privacy Rules, a "County Overall Status" category has been introduced in Attachment C because Security planning is being done at the County level and it would be awkward, and probably misleading, to attempt to report status on HIPAA Security department-by-department. Both DHS and DMH have either done or are doing security assessments as part of their overall HIPAA assessments. They know that they have security issues that do not exist in other County departments that will be difficult to address in the 24 months following finalization of the Security Rules.

The County has not waited for the final HIPAA Security rules to get started. The County's Cyber Terrorism Task Force is working towards a comprehensive, coherent security program. Security will be a continuing responsibility of the County as long as we have information assets that can be compromised.

Critical to this continuing security program is hiring a Chief Information Security Officer (CISO) for the County. A bulletin is being prepared for release in the near future. DHR posted a bulletin for an Information Security Specialist, a supporting position to the CISO, on May 20, 2002.

County Actions and Planned Expenditures

Contract work authorized to date for HIPAA-related activities totals \$11.6 million. Of this amount, \$2.9 million was spent on or before April 30, 2002. There are consultant deliverables in the review and approval process, so the amount spent can be expected to increase by the next report.

The next HIPAA Status Report to the Board will be submitted on August 26, 2002.

If you have questions or require additional information, please contact me at (213) 974-2008.

DEJ:JWF:ygd

Attachments

c: David E. Janssen
Executive Officer, Board of Supervisors
Department Heads

Summary of HIPAA-Related Contract Expenses for Los Angeles County

Attachment A

Dept.	HIPAA Section	Vendor	Description	County Agreement No.	Board Approval Date Where Applicable	Agreement Term	Authorized Amount	HIPAA Expenditures as of 04/30/2002	Remaining Authorization	Estimated HIPAA Amount	Status
DHS	Transactions & Code Sets, Privacy, Security, Unique Identifiers	Comdisco	Primary HIPAA assessment and compliance plan consultant. Includes a Security assessment subcontract.	ITSSMA work order # N78-0008		4/10/2001 through 5/12/2002	\$1,115,000	\$875,000	\$240,000	\$1,115,000	Comdisco sold to GE and this contract expired 5/12/2002. Some deliverables remain to be paid. All outstanding work assigned to N78-0021.
DHS	Transactions & Code Sets, Privacy, Security, Unique Identifiers	SecureSoft	Primary HIPAA assessment and compliance plan consultant. These includes Personal Health, Public Health and OMC.	ITSSMA work order # N78-0021		5/13/2002 through 4/10/2003	\$2,360,000	\$0	\$2,360,000	\$2,360,000	Assessments/gap analyses occurring simultaneously, recommendations in draft form. The TCI team is working on data mapping.
DHS	Transactions & Code Sets, Privacy, Security, Unique	Modis	DHS Data Repository programming support.	H-209555	6/19/2001	7/1/2001 through 6/30/2004	\$422,880	\$26,353	\$396,527	\$105,720	HIPAA work is in progress.
DHS	Transactions & Code Sets	Ladera Career Path, Inc.	Medical Records coding and abstracting.	H-205964							The HIPAA portion of this contract allows DHS to begin to capture additional data related to HIPAA transactions and code sets.
		Records Technician Services, Inc.		H-205965							
		Jenn International Personnel Agency		H-205967							
		Certus Corporation		73249-1							
		Hospital Employee Labor Pool		H-205962	6/26/2001	7/1/2001 through 12/31/2002					
DHS Sub-total							\$8,847,880	\$1,981,469	\$6,866,411	\$5,280,720	

5/28/2002

Summary of HIPAA-Related Contract Expenses for Los Angeles County

Attachment A

Dept.	HIPAA Section	Vendor	Description	County Agreement No.	Board Approval Date	Agreement	Authorized Amount	HIPAA Expenditures as of 04/30/2002	Remaining Authorization	Estimated HIPAA Amount	Status
DMH	Transactions & Code Sets	Fox Systems	DMH Transactions & Code Sets consultant - assessment & compliance plan	work order # N7E-0007		5/16/2001 through 08/31/02	\$941,400	\$784,368	\$157,032	\$941,400	Plan completed
DMH	Transactions & Code Sets	HL Yoh	DMH Transactions & Code Sets consultant - compliance support				\$195,000	\$65,000	\$130,000	\$195,000	Ongoing support
DMH	Privacy/ Security	CLD Group	DMH Privacy & Security consultant - assessment & compliance plan	Purchase Order S41521	N/A	10/31/2001	\$45,000	\$45,000	\$0	\$45,000	Report adopted
DMH Sub-total							\$1,181,400	\$894,368	\$287,032	\$1,181,400	RFI in Process
County Counsel	Transactions & Code Sets, Privacy, Security, Unique Identifiers	Foley & Lardner	Foley & Lardner, working under existing agreement to provide outside counsel services to County, is providing expert legal guidance on coverage of and compliance with HIPAA (amounts shown are approximate)	Blanket	5/1/1997	Continuing	\$30,000	\$30,000 *		\$30,000	Continuing to work with the Service Integration Branch.
County Counsel Sub-total							\$30,000	\$30,000		\$30,000	
CIO	Security (County-wide)	TBD	County-wide security assessment & plan	N/A				\$0			A Statement of Work for an RFP has been drafted and ISD has been contacted to begin the procurement process.
CIO	Privacy (County-wide)	Foley & Lardner	Legal advice coordinated through County Counsel related to HIPAA Privacy Rules	Blanket	5/1/1997	Continuing	\$1,550,000		\$1,550,000	\$1,550,000	An approach has been outlined with Robyn Meinhart of Foley & Lardner and plans are being made to initiate the work with departments, coordinated through County Counsel.
CIO	Privacy (County-wide)	TBD	Consulting assistance for HIPAA Privacy compliance implementation	N/A				\$25,353			This item is on hold pending the findings of Privacy work begun with Foley & Lardner.
CIO Sub-total							\$1,550,000	\$25,353	\$1,550,000	\$1,550,000	
County Total							\$11,609,280	\$2,931,190	\$8,703,443	\$8,042,120	

* Estimated amount pending receipt of final invoices.

5/28/2002

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BOS_HIPAAConsolidated Contract Summary_May_rmg

Summary of HIPAA-Related Expenditures with ISD/ITS for Los Angeles County

Attachment B

Dept.	HIPAA Section	Description	HIPAA Expenditures to Date	Planned Expenditures this FY	Planned Expenditures FY 2002/2003	Status
DHS						Nothing to report.
	Transactions & Code Sets, Privacy, Security, Unique Identifiers	ISD is working closely with DMH on all assessment, gap analysis, and remediation tasks related to the Mental Health Information System hosted on the ISD mainframe.	\$242,418			DMH and ISD/ITS expect significant increases in expenditures this fiscal year and next. However, at this time the departments are developing a useful projection of the amounts and will provide them following evaluation of vendor solutions.
County Total			\$242,418			

HIPAA Impact on LA County Departments – May 2002 Update

Attachment C

Level of Impact Key:

1=major impact (On the scale of Y2K or greater)

2=significant impact (clearly smaller than Y2K, but still requiring a team effort to accomplish)

3=minor impact

0=no impact

(?)=level of impact in question until implications of the Privacy NPRM fully assessed.

Schedule Key:

■ = on schedule

■ = less than 30 days behind schedule (caution)

■ = more than 30 days behind schedule (warning)

Ability to Meet Deadline Key:

■ = based on current information, it appears achievable

■ = there are significant obstacles or areas of uncertainty or concerns about resources (caution)

■ = there are clearly identifiable threats or resources significantly below requirements (warning)

Department		Transactions & Code Sets	Privacy	Security	Comment
County Overall Status	Level of Impact	1 (Deadline 10/16/2002)	1 (Deadline 4/14/2003)	1 (Anticipated deadline about 9/2004)	The status indicated under Transactions and Code Sets reflects issues described in detail in the DHS and DMH sections below. The schedule status remains at a warning level, however, and will remain so until the County files for the one-year extension to the deadline allowed by Federal legislation. It is in the County's interests to request such an extension.
	Schedule	■			Security is being assessed at the County level, taking into account work at DHS and DMH because of their urgent need to get an early assessment of their status. While the final security rules have not been published, there are few changes expected from the draft rules and the County will be significantly challenged to achieve full compliance within the allotted 26 months after final publication of the rules. The CIO is attempting to get an early start to give the County the best possible chance of succeeding. The Cyber Terrorism Task Force has developed proposals that move the County towards a security program that will meet HIPAA requirements. While this activity is more than 30days behind schedule, the color coding is left at the caution level because there is no fixed deadline yet for the Security regulations.
	Ability to Meet Deadline				
					DHR has posted a bulletin for a Security Specialist position in the CIO's office and a bulletin is expected to be released in the near future for an Information Security Officer position.
					Much of the Privacy work is at the department level, however, the County is establishing an Information Privacy Officer (IPO) position in the CIO's Office per HIPAA requirements. DHR has posted the bulletin for the IPO.

Department		Transactions & Code Sets	Privacy	Security	Comment																																																		
Department of Health Services	Level of Impact	1 (Deadline 10/16/2002)	1 (Deadline 4/14/2003)	1 (Anticipated deadline about 9/2004)	PROJECT SCHEDULE: All three assessments and gap analysis are occurring simultaneously. The HIPAA consultant has completed the following: <table><tr><td></td><td><u>Personal Health</u></td><td><u>Public Health</u></td><td><u>OMC</u></td><td><u>OVERALL</u></td></tr><tr><td>TCI: Current State Assessment</td><td>100%</td><td>8%</td><td>6%</td><td>38.0%</td></tr><tr><td>Gap Analysis</td><td>96%</td><td>8%</td><td>6%</td><td>36.7%</td></tr><tr><td>Recommendations</td><td>96%</td><td>0%</td><td>0%</td><td>32.0%</td></tr><tr><td>Privacy: Current State Assessment</td><td>100%</td><td>35%</td><td>60%</td><td>65.0%</td></tr><tr><td>Gap Analysis</td><td>45%</td><td>35%</td><td>60%</td><td>46.7%</td></tr><tr><td>Recommendations</td><td>45%</td><td>0%</td><td>0%</td><td>15.0%</td></tr><tr><td>Security: Current State Assessment</td><td>100%</td><td>35%</td><td>60%</td><td>65.0%</td></tr><tr><td>Gap Analysis</td><td>100%</td><td>35%</td><td>60%</td><td>65.0%</td></tr><tr><td>Recommendations</td><td>100%</td><td>0%</td><td>0%</td><td>33.3%</td></tr></table> <p>Comdisco, the DHS contract consultant performing their HIPAA assessments, gap analyses, and planning, has been sold. The DHS contract has been assigned to SecureSoft to complete the work in Public Health, Juvenile Court Health Services, and the Office of Managed Care. The work expected to be complete in June 2002.</p> <p>ABILITY TO MEET DEADLINE: DHS is working with County Counsel, among others, on the issue of whether DHS will be forced to produce itemized claims as the result of HIPAA. DHS currently bills on an all-inclusive rate basis (summary bill). HIPAA mandates the use of the X.12N 837 Health Care Claim (837) for transmission of electronic claims or encounter information. The 837 standardizes the format and content of the claim. DHS has sent a letter to the California State DHS stating the county's position on all-inclusive billing and recommendations on how it can be continued under HIPAA. The State has acknowledged the letter and indicated they are working on a response. The opportunity provided by HR 3233 to request an extension of the TCI deadline to October 2003 will provide DHS with time to resolve this issue with the State, but an unfavorable State ruling could still threaten DHS's ability to meet even the 2003 TCI deadline.</p> <p>DHS is working with County Counsel regarding the substantial impact of HIPAA on provider and other contracts</p>		<u>Personal Health</u>	<u>Public Health</u>	<u>OMC</u>	<u>OVERALL</u>	TCI: Current State Assessment	100%	8%	6%	38.0%	Gap Analysis	96%	8%	6%	36.7%	Recommendations	96%	0%	0%	32.0%	Privacy: Current State Assessment	100%	35%	60%	65.0%	Gap Analysis	45%	35%	60%	46.7%	Recommendations	45%	0%	0%	15.0%	Security: Current State Assessment	100%	35%	60%	65.0%	Gap Analysis	100%	35%	60%	65.0%	Recommendations	100%	0%	0%	33.3%
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Department of Mental Health	Level of Involvement	1 (Deadline 10/16/2002)	1 (Deadline 4/14/2003)	1 (Anticipated deadline about 9/2004)	Assessments, gap analyses, and the remediation plan have been completed and adopted by DMH for Transactions and Code Sets (T&CS), Privacy, and Security. The Security assessment must be considered preliminary because the Security regulations have not been finalized and the Security assessment was done at a relatively high level.
					DMH is in the early stages of a procurement effort to retain a contractor to perform work related to the Transactions and Code Sets portion of the Remediation Plan. The work cannot be done by County staff. They are on a very aggressive schedule and hope to have a contract signed by September 2002.
	Schedule				DMH has identified a Privacy Officer.
	Ability to Meet Deadline				DMH is working with County Counsel on provider and other contract language that will need modification as a result of HIPAA. Significant revisions to its policies and procedures with respect to client records will be necessary. DMH has focused internal resources on improving information security, but anticipates requiring major investments in new plant, material, staffing and technology to comply with the anticipated level of security required by HIPAA.
Sheriffs Department	Ability to Meet Deadline	0	1(?)	1(?)	For T&CS and Privacy, DMH has stated that it has project resource identification issues.
	Level of Impact				
	Schedule	N/A			The HIPAA Privacy Notice of Proposed Rule Making (NPRM) described in the cover memo directly impacts the Sheriffs Department status with regard to HIPAA. After reviewing their status as part of the May 1, 2002, special session of the HIPAA Compliance Task Force devoted to the NPRM, the Task Force and the Sheriffs Department were in concurrence that a follow-up session was necessary and would include, at a minimum, Sheriffs Department staff, the Chair of the HIPAA Compliance Task Force, County Counsel, and Foley and Lardner. This meeting has not yet been scheduled yet.
	Ability to Meet Deadline	N/A			The only portion of the Sheriff's operation that appears to be directly impacted by the Privacy Rules, and probably the Security Rules when they are finalized, is the Medical Services Bureau of the Custody Division.
Department of Public Social Services	Level of Impact	0	2(?)	2(?)	DPSS is one of the departments that clearly benefits from the changes in the NPRM. They do not perform any of the HIPAA transactions, so they have a choice whether to be included in the health care component of the County hybrid entity. At this point it appears that there is no benefit to DPSS or other County departments from including DPSS in the health care component. A formal recommendation will be forwarded to the Board at a later date.
	Schedule	N/A			
	Ability to Meet Deadline	N/A			

Department		Transactions & Code Sets	Privacy	Security	Comment
Probation Department	Level of Impact Schedule Ability to Meet Deadline	2 N/A	(Deadline 4/14/2003) 2	(Anticipated deadline about 9/2004) 2	The Probation Department, as the result of its continuing HIPAA assessment, has found that, while it does not perform any of the HIPAA transactions, DMH does execute the health care claim transaction on its behalf. Under HIPAA, it is just as if Probation did the transaction. This transaction is performed for one program running at one site. If the program remains as it is now, under the Privacy NPRM, Probation will be a required member of the health care component of the County hybrid entity. Probation is examining its options. The status shown for T&CS reflects the status of DMH because DMH is handling the transaction in question.
Department of Children & Family Services	Level of Impact Schedule Ability to Meet Deadline	0 N/A	2 N/A	2	The HIPAA Privacy NPRM directly impacts DCFS status with regard to HIPAA. After reviewing their status as part of the May 1, 2002, special session of the HIPAA Compliance Task Force devoted to the NPRM, the Task Force and DCFS Department were in concurrence that a follow-up session was necessary and that it would address both DCFS and MacLaren Hall because the issues were similar. The meeting is scheduled for May 31, 2002, and will include DCFS staff, DMH, DHS, the CAO, the Chair of the HIPAA Compliance Task Force, County Counsel, and Foley and Lardner.
Department of Community & Senior Services (Adult Protective Services)	Level of Impact Schedule Ability to Meet Deadline	0 N/A	2(?)	2(?)	DCSS (APS) is one of the cases where the changes proposed in the Privacy NPRM gave a department an unambiguous choice. APS has some activity that meets the HIPAA definition of health care, but they do not perform any of the HIPAA transactions. They can choose to be either in or out of the health care component of the hybrid entity, but in the case of APS, there appear to be clear disadvantages that would interfere with the conduct of its duties.
Department of Human Resources (Occupational Health)	Level of Impact Schedule Ability to Meet Deadline	0 N/A	2(?)	2(?)	A formal recommendation will be forwarded to the Board at a later date.
Department of Coroner	Level of Impact Schedule Ability to Meet Deadline	0 N/A	2(?)	2(?)	DHR is in much the same situation as APS. It can choose to be in or out of the health care component based on the Privacy NPRM changes, but there are clear disadvantages to choosing to be included in the health care component.
Department of Treasurer and Tax Collector	Level of Impact Schedule Ability to Meet Deadline	3 N/A	2	2	A formal recommendation will be forwarded to the Board at a later date.
					No change in status: TTC is primarily in a supporting role for DHS and DMH. All protected health information that passes through T&TC originates in either DHS or DMH. T&TC and DMH are jointly addressing the impact on T&TC. This work has not been initiated with DHS at the time of this report.

Department		Transactions & Code Sets (Deadline 10/16/2002)	Privacy (Deadline 4/14/2003)	Security (Anticipated deadline about 9/2004)	Comment
Department of Military & Veterans Affairs	Level of Impact	0	3	0	The Privacy NPRM clarifies the status of DMVA with regard to HIPAA. DMVA does not provide health care nor does it execute HIPAA transactions. There is no justification for including it in the health care component of the County hybrid entity.
	Schedule	N/A			
	Ability to Meet Deadline	N/A			
Internal Services Department	Level of Impact	2	3	1	A formal recommendation will be forwarded to the Board at a later date.
	Schedule				
	Ability to Meet Deadline				
Department of Auditor Controller	Level of Impact	2	2	2	All protected health information that passes through A-C originates in either DHS or DMH. ISD is an active participant in DMH and DHS HIPAA compliance efforts. They are working with DMH to obtain appropriate consulting assistance to execute its remediation plan. The caution level status under Transactions and Code Sets signifies concern about the resources necessary to assist DMH with meeting the Transaction and Code Sets deadline.
	Schedule				
	Ability to Meet Deadline				
					All protected health information that passes through A-C originates in either DHS or DMH. The Privacy and Security of this information is being addressed as part of the compliance plans of DHS and DMH. A-C is working with DMH and DHS with regard to TCI issues.

HIPAA Transactions and Code Sets Compliance Work Plan **Los Angeles County**

Attachment D

ID	Task Name	Duration	Base Start	Base Finish	Act. Start	Act. Finish
1	Schedule initial meeting of HIPAA Compliance Task Force	1.4 wks	7/27/00	8/4/00	8/1/00	8/9/00
2	Develop Agenda for Initial Meeting	0.2 wks	8/7/00	8/7/00	8/16/00	8/16/00
3	Notify Attendees	2.8 wks	8/8/00	8/25/00	8/17/00	9/5/00
4	Conduct initial meeting	1 day	9/6/00	9/6/00	9/6/00	9/6/00
5	Conduct regularly scheduled HIPAA Task Force Meetings	600 days	10/5/00	1/22/03	9/20/00	NA
6	Develop HIPAA work plan	7.6 wks	9/7/00	9/20/00	9/7/00	10/30/00
7	Establish compliance program	7.6 wks	9/7/00	10/18/00	9/7/00	10/30/00
8	Educate as necessary	273 days	9/7/00	1/24/01	9/13/00	9/28/01
9	Identify potential speakers, conferences, training, etc.	54.6 wks	9/7/00	1/1/00	9/13/00	9/28/01
10	Work with departments to select opportunities	52 wks	9/7/00	1/1/00	10/1/00	9/28/01
11	Obtain approval for speakers, etc.	35 wks	10/19/00	1/15/00	1/29/01	9/28/01
12	Schedule conferences/presentation	216 days	11/29/00	1/129/00	12/1/00	9/28/01
13	Conduct/attend conferences/presentations	34 wks	11/30/00	1/24/01	2/5/01	9/28/01
14	Evaluate need for outside assistance & obtain if necessary	43 days	9/21/00	1/1/00	9/21/00	11/20/00
15	Identify specific initial consulting services required	43 days	9/21/00	1/1/00	9/21/00	11/20/00
16	ID systems with HIPAA transactions	43 days	9/21/00	10/4/00	9/21/00	11/20/00
17	ID operational units involved w/ transactions/code sets	43 days	10/5/00	10/18/00	9/21/00	11/20/00
18	ID contractors involved with HIPAA transactions	43 days	10/5/00	10/5/00	9/21/00	11/20/00
19	ID procedures, policies, forms, training impacted	43 days	10/12/00	1/1/00	9/21/00	11/20/00
20	Identify means of acquisition	44 days	9/21/00	10/4/00	10/15/00	12/14/00
21	Identify funding	28 days	10/5/00	10/11/00	11/15/00	12/24/00
22	Prepare procurement documents	289 days	10/12/00	10/25/00	11/15/00	12/24/01
23	Process procurement	0 wks	11/9/00	12/6/00	2/10/01	2/10/01
24	Departmental Assessment/Gap Analysis	195 days	12/7/00	2/22/01	4/10/01	NA
25	Identify areas to assess	159 days	12/7/00	12/8/00	4/10/01	11/16/01
26	Identify potential tools	159 days	12/11/00	12/12/00	4/10/01	11/16/01
27	Determine assessment approach	159 days	12/11/00	12/12/00	4/10/01	11/16/01
28	Identify assessment team	159 days	12/11/00	12/12/00	4/10/01	11/16/01
29	Schedule Assessment	159 days	12/13/00	12/14/00	4/10/01	11/16/01
30	Conduct/document Assessment	40 days	12/15/00	2/8/01	4/10/01	11/16/01
31	Evaluate gaps between regulations & current environment	10 days	2/9/01	2/22/01	4/10/01	NA
32	Document gaps	5 days	2/16/01	2/22/01	4/10/01	NA
33	Develop a plan to close the gap	30 days	2/23/01	4/5/01	4/10/01	NA
34	Obtain Departmental approval of Plan	3 days	4/6/01	4/10/01	4/10/01	NA
35	Obtain CIO/HIPAA Task Force approval of plan	10 days	4/11/01	4/24/01	4/4/02	NA
36	Obtain necessary approvals and resources	30 days	4/25/01	6/5/01	4/25/01	NA
37	Execute the plan and monitor execution	325 days	6/6/01	9/3/02	4/17/02	NA
38	Test Transactions	190 days	1/4/02	9/26/02	NA	NA
39	Evaluate compliance program	80 days	9/4/02	12/24/02	NA	NA
40	Continue compliance program	1000 days	12/25/02	10/24/06	NA	NA

HIPAA Privacy Compliance Work Plan Los Angeles County

Attachment E

ID	Task Name	Duration	Bstart	Bfinish	Act Start	Act Finish	Comments
1	Assessment	63 d	10/1/01	1/18/02	10/1/01	NA	
2	Identify where Protected Health Information (PHI) is used	40 d	10/1/01	11/23/01	10/1/01	NA	PHP & OMC in progress
3	Identify Sources of PHI	40 d	10/1/01	11/23/01	10/1/01	NA	DMH has completed this
4	Determine if PHI use continues to be necessary	5 d	11/19/01	11/23/01	10/23/01	NA	DMH has completed this
5	Gather existing policies and procedures related to PHI	40 d	11/26/01	1/18/02	11/1/01	NA	DMH has completed this
6	Identify existing privacy laws to which you comply	40 d	1/14/02	1/18/02	11/1/01	NA	DMH has completed this
7	Schedule Initial Gap Analysis Meeting	5 d	1/14/02	1/18/02	10/15/01	NA	DMH has completed this
8	Gap Analysis	118 d	1/21/02	3/1/02	9/10/01	NA	
9	Determine where an Authorization is required to obtain PHI	10 d	1/21/02	2/1/02	10/23/01	NA	
10	Identify impact on contracts or business partner relationships	10 d	1/21/02	2/1/02	10/10/01	NA	
11	Identify other HIPAA Privacy impacts on use of PHI	20 d	1/21/02	2/15/02	10/2/01	NA	
12	Identify HIPAA conflicts with existing State law	20 d	1/21/02	2/15/02	10/15/01	NA	
13	Identify any new policies and procedures or those that require modifica	20 d	1/28/02	2/22/02	9/10/01	NA	
14	Identify any IT impact	20 d	2/4/02	3/1/02	1/24/02	NA	
15	Identify staffing and training impacts	20 d	2/4/02	3/1/02	9/17/01	NA	
16	Develop Remediation Plan	80 d	3/4/02	6/21/02	1/24/02	NA	
17	Resolve issues with HIPAA and existing law	20 d	3/4/02	3/29/02	1/24/02	NA	
18	Authorizations	20 d	3/4/02	3/29/02	1/24/02	NA	
19	Contracts	20 d	3/4/02	3/29/02	1/24/02	NA	
20	Policy and Procedures	20 d	3/4/02	3/29/02	1/24/02	NA	
21	IT	40 d	3/4/02	4/26/02	1/24/02	NA	
22	Staffing and Training	40 d	3/4/02	4/26/02	1/24/02	NA	
23	Funding	20 d	4/29/02	5/24/02	NA	NA	
24	Approvals	30 d	5/13/02	6/21/02	NA	NA	
25	Execute Remediation Plan and Train Staff	170 d	6/24/02	2/14/03	NA	NA	
26	Develop necessary authorizations	40 d	6/24/02	8/16/02	NA	NA	
27	Modify contracts as necessary	60 d	6/24/02	9/13/02	NA	NA	
28	Modify information systems as necessary	80 d	7/8/02	10/25/02	NA	NA	
29	Develop or modify policies and procedures as necessary	60 d	8/5/02	10/25/02	NA	NA	
30	Acquire, re-assign, or train staff as necessary	160 d	7/8/02	2/14/03	NA	NA	

HIPAA Privacy Compliance Workplan for Non-Healthcare Components Attachment F

(Users of Protected Health Information)

Los Angeles County

ID	Task Name	Duration	Base Start	Base Finish	Act Start	Act Finish
1	Assessment	63 d	10/1/01	1/18/02	10/1/01	NA
2	Identify where Protected Health Information (PHI) is used	40 d	10/1/01	11/23/01	10/1/01	NA
3	Identify Sources of PHI	40 d	10/1/01	11/23/01	10/1/01	NA
4	Determine if PHI use continues to be necessary	5 d	11/19/01	11/23/01	10/23/01	NA
5	Gather existing policies and procedures related to PHI	40 d	11/26/01	1/18/02	11/1/01	NA
6	Identify existing privacy laws to which you comply	40 d	11/26/01	1/18/02	11/1/01	NA
7	Schedule initial Gap Analysis Meeting	5 d	1/14/02	1/18/02	10/15/01	NA
8	Assess Impact of Privacy Notice of Proposed Rule Making (NPRM)	95 d	3/27/02	8/6/02	3/27/02	NA
9	Preliminary evaluation of proposed changes and impact on County	35 d	3/27/02	5/14/02	3/27/02	5/14/02
10	Follow-up assessment sessions with complex departments	30 d	5/15/02	6/25/02	5/15/02	NA
11	Formulate Recommendations to the Board	10 d	6/26/02	7/9/02	NA	NA
12	Submit Recommendations to the Board	5 d	7/10/02	7/16/02	NA	NA
13	Board approves Recommendations	15 d	7/17/02	8/6/02	NA	NA
14	Gap Analysis	81 d	1/21/02	3/1/02	10/10/01	NA
15	Determine where an Authorization is required to obtain PHI	10 d	1/21/02	2/1/02	10/23/01	NA
16	Identify impact on contracts or business partner relationships	10 d	1/21/02	2/1/02	10/10/01	NA
17	Identify other HIPAA Privacy impacts on use of PHI	20 d	1/21/02	2/15/02	11/27/01	NA
18	Identify HIPAA conflicts with existing State law	20 d	1/21/02	2/15/02	11/27/01	NA
19	Identify any new policies and procedures or those that require modifica	20 d	1/28/02	2/22/02	NA	NA
20	Identify any IT impact	20 d	2/4/02	3/1/02	NA	NA
21	Identify staffing and training impacts	20 d	2/4/02	3/1/02	NA	NA
22	Develop Remediation Plan	80 d	3/4/02	6/21/02	NA	NA
23	Resolve issues with HIPAA and existing law	20 d	3/4/02	3/29/02	NA	NA
24	Authorizations	20 d	3/4/02	3/29/02	NA	NA
25	Contracts	20 d	3/4/02	3/29/02	NA	NA
26	Policy and Procedures	20 d	3/4/02	3/29/02	NA	NA
27	IT	40 d	3/4/02	4/26/02	NA	NA
28	Staffing and Training	40 d	3/4/02	4/26/02	NA	NA
29	Funding	20 d	4/29/02	5/24/02	NA	NA
30	Approvals	30 d	5/13/02	6/21/02	NA	NA
31	Execute Remediation Plan and Train Staff	170 d	6/24/02	2/14/03	NA	NA
32	Develop necessary authorizations	40 d	6/24/02	8/16/02	NA	NA

HIPAA Privacy Compliance Workplan for Non-Healthcare Components Attachment F **(Users of Protected Health Information)** **Los Angeles County**

ID	Task Name	Duration	Base Start	Base Finish	Act Start	Act Finish
33	Modify contracts as necessary	60 d	6/24/02	9/13/02	NA	NA
34	Modify information systems as necessary	80 d	7/8/02	10/25/02	NA	NA
35	Develop or modify policies and procedures as necessary	60 d	8/5/02	10/25/02	NA	NA
36	Acquire, re-assign, or train staff as necessary	160 d	7/8/02	2/14/03	NA	NA

HIPAA Security Compliance Work Plan **Los Angeles County**

Attachment G

ID	Task Name	Duration	Bstart	Bfinish	Act Start	Act Finish	Comments
1	Final Rule Published (Estimated)	0 days	12/31/01	12/31/01	NA	NA	
2	Final Rule Effective (Estimated)	44 days	1/1/02	3/1/02	NA	NA	
3	Create LA County Security Office with CIO	120 days	9/3/01	2/15/02	9/3/01	NA	awaiting authority to hire and assignment of appropriate pay level
4	Obtain Consulting Assistance	101 days	9/3/01	1/21/02	9/3/01	NA	
5	Draft SOW	20 days	9/3/01	9/28/01	9/3/01	9/28/01	
6	Get internal approvals	5 days	10/1/01	10/5/01	10/1/01	10/5/01	on hold pending cyber-terrorism workgroup results
7	Get concurrence from ISD, County Council	30 days	10/8/01	11/16/01	10/8/01	NA	
8	Notify Board of ITSSMA Solicitation	15 days	11/19/01	12/7/01	NA	NA	
9	Release ITSSMA Solicitation	0 days	12/7/01	12/7/01	NA	NA	
10	Evaluate Responses	5 days	12/31/01	1/4/02	NA	NA	
11	Select Vendor	1 day	1/7/02	1/7/02	NA	NA	
12	Finalize Contract	10 days	1/8/02	1/21/02	NA	NA	
13	Begin Work	0 days	1/21/02	1/21/02	NA	NA	
14	Assessment	120 days	1/22/02	7/8/02	4/10/01	NA	DMH has completed its assessment. DHS still in progress for PHP and OMC
15	Gap Analysis	90 days	7/9/02	11/11/02	9/25/01	NA	DMH has completed its gap analysis. DHS still in progress for PHP and OMC
16	Remediation Plan	90 days	11/12/02	3/17/03	1/29/02	NA	DMH developed a high-level remediation plan, but at this point not integrated into a County security approach
17	Execute Plan	240 days	3/18/03	2/16/04	NA	NA	



**COUNTY OF LOS ANGELES
OFFICE OF THE COUNTY COUNSEL**

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County Counsel

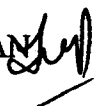
May 16, 2002

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TO: SUPERVISOR ZEV YAROSLAVSKY, Chairman
SUPERVISOR GLORIA MOLINA
SUPERVISOR YVONNE BRATHWAITE BURKE
SUPERVISOR DON KNABE
SUPERVISOR MICHAEL D. ANTONOVICH

FROM: LLOYD W. PELLMAN 
County Counsel

RE: **Proposed Changes to Federal Privacy Regulations (HIPAA)**

As you may be aware, the federal Department of Health and Human Services ("DHHS") has announced proposed changes to the privacy regulations previously adopted to implement the Health Insurance and Portability Act of 1996 ("HIPAA"). This memorandum is intended to give you a brief summary of the proposed changes, and to inform you that the County's HIPAA Task Force is carefully reviewing them to determine their impact on County departments.

We are assisted in HIPAA legal matters by our outside counsel, Foley and Lardner. Robyn Meinhardt from the firm is a nationally recognized expert in HIPAA and has assisted the HIPAA Task Force for over a year regarding implementation efforts. Ms. Meinhardt has provided a written summary of her preliminary reactions to the proposed regulations, a copy of which is enclosed in the event you wish additional information about the changes. In addition, the Task Force, with representatives from affected County departments, will be meeting with Ms. Meinhardt to discuss the impact of these proposed changes. The Task Force will keep your Board informed of all significant developments.

It needs to be emphasized at this point that these regulations are not final and are themselves subject to change. It may be several months before they are in their final form.

SUMMARY OF MAJOR ELEMENTS OF PROPOSED CHANGES

- **Consent and Notice Provisions**

This is the area that has received the most publicity. Responding to concerns that the existing HIPAA regulations place unintended impediments to the provision of health care, DHHS proposes eliminating the requirement of formal consent to use Protected Health Information ("PHI") for treatment, payment, or health care operations. There is still a requirement to obtain an individual's "written acknowledgment of receipt" of privacy practices. Because there are state laws regarding consents and authorizations, we will need to carefully review the proposal to determine its impact on state law and the County's practices.

- **Hybrid Entity Rules**

The "hybrid entity" concept in HIPAA has had significant implications for the County and other governmental entities for which the provision of "health care" is not their sole or primary function. Under the existing regulations, the County itself is a "hybrid entity" under HIPAA, with those departments providing "health care" as "covered" components. Clearly, the Departments of Health Services ("DHS") and Mental Health ("DMH") are covered components, and this designation will not change under the new regulations. The HIPAA Task Force has spent months reviewing other departments to determine whether, based on their functions, they are also "covered components."

Under the regulations applicable to "hybrid entities," the County is ultimately accountable for HIPAA compliance, while the specifics of HIPAA's regulations (transactions and code sets, privacy, and security) apply only to its "covered components."

The proposed new regulations appear to change the nature of this determination, and may create a policy choice which has not previously existed. As Ms. Meinhardt writes, "If the proposed change becomes law, the hybrid entity may make a business decision as to which is better for the organization."

Specifically, the County could deem itself a "hybrid entity" and designate those departments, or parts of departments, which provide health care as "covered components." In the alternative, the County could choose not to designate any of its departments as "health care components," in which case the County, in its entirety, would be considered a covered entity. The Task Force will carefully review these options and forward a recommendation to your Board.

- **Possible Delay in Effective Date for "Business Associates" Contracts**

Under HIPAA, "Business Associates" are entities other than providers of medical treatment with which the County contracts to provide services "on behalf of" the County, and which receive PHI in the course of the provision of services. The County must have detailed contract provisions with such Business Associates related to the privacy of medical information. The new rules propose a delay in the effective date of these required contractual changes. Outside counsel and my office believe, however, that we should include these provisions in all new contracts, in advance of the effective date, to insure adequate notice and compliance, and to allow for contracts to be developed, amended, or renewed in a timely manner.

- **Parents and Minors**

Although the proposed new regulations assert that their purpose regarding minor consent and parental access is to simply "better implement" the existing approach to defer to state law, outside counsel advises that, if they become final, the County will need to "pay particular attention to policy development and provider training" on these issues.

- **Additional Issues**

There are other aspects to the proposed regulations, which are commented on in detail in the enclosure. We intend to carefully review all the potential impacts, and will keep you informed as appropriate.

Additional questions were posed to DHS regarding the proposed regulations. They are (1) will they affect the number of medical malpractice claims sent to the Board, and (2) does DHS have an appropriate plan to insure that its staff is handling medical records accordingly? We have reviewed this with DHS and jointly respond that, based on our current understanding of the

regulations, they will probably not, by themselves, have a significant effect on malpractice claims, but they may well lead to an increase in claims alleging a breach of confidentiality. DHS and DMH will, as part of their overall HIPAA implementation effort, be required to provide appropriate training regarding the privacy and security of medical records.

Should you have any additional questions, please feel free to contact Dr. Robert Greenless of the CIO's office at 974-1894, or Principal Deputy County Counsel Richard Mason at 974-0687.

LWP:RKM:if

Enclosure

c: David E. Janssen
Chief Administrative Officer

Violet Varona-Lukens
Executive Officer, Board of Supervisors

Jon W. Fullinwider
Chief Information Officer

Thomas L. Garthwaite, M.D.
Director and Chief Medical Officer, Department of Health Services

Robert Greenless, Ph.D.
Associate, Chief Information Office

Fred Leaf
Chief Operating Officer, Department of Health Services

Marvin J. Southard, D.S.W.
Director, Department of Mental Health

FOLEY LARDNER MEMORANDUM

CLIENT-MATTER NUMBER
153335-0252

TO: Richard Mason
Robert Greenless

FROM: Robyn A. Meinhardt

CC: Denise Rodriguez

DATE: March 26, 2002

RE: Proposed Changes to Privacy Rules and Their Potential Impact on the County

As you know, the federal Department of Health and Human Services (DHHS) has just announced proposed changes to the privacy standards under the Health Insurance Portability and Accountability Act (HIPAA), through a formal Notice of Proposed Rulemaking (NPRM). I've reviewed the rules and thought you'd be interested in preliminary conclusions as to how the proposals affect the County. Some of the proposals significantly affect the County's HIPAA implementation efforts to date, many of them in a positive or neutral way, but several will require the County to rethink its approach to its designation of covered function components, and its role as a hybrid entity in general.

These preliminary thoughts are intended as a place to start a more in-depth analysis of the changes that will be wrought by the new rules, whatever they turn out to be in final form. DHHS will receive comments on the proposed changes over the next 30 days, and will then take those comments into account when it publishes the final version of these proposed changes. We probably will not see the final version until late in May at the earliest, although it seems more likely that it will be released sometime this summer. DHHS believes that the HIPAA statute requires any changes to be in place by October.

Consent and Notice. By far, the greatest publicity surrounding the proposed changes has focused on the proposal to remove the consent requirement, making consent optional for those who feel they must obtain it for ethical or state law reasons. This proposal has less actual impact than it might otherwise, because the proposal also includes the requirement that *covered health care providers with direct treatment relationships* (not indirect providers, health plans or clearinghouses) attempt to obtain an individual's "written acknowledgement of receipt" of the Notice of Privacy Practices at the time of first service delivery. DHHS prefers a signature, although the individual's initials will suffice. If the patient refuses to provide the written acknowledgement, the covered health care provider must document the attempt and the refusal and may thereafter use and disclose the patient's PHI for treatment, payment and health

care operations activities, consistent with the provisions in the Notice. Attempts to obtain the written acknowledgement may be delayed in emergency treatment situations.

DHHS does not propose requiring this "written acknowledgement" for subsequent versions of the Notice. Neither does it revise any of the mandatory provisions to be included in the Notice. However, failure to create and retain the documentation for either the "written acknowledgement," or the good faith attempt to obtain the acknowledgement and the reasons for failure to do so, will cause a violation of HIPAA if the individual's PHI is thereafter used or disclosed, even for treatment, payment or health care operations purposes.

Potential Impact on the County: It seems likely that the consent requirement will be eliminated in the next official version of the rules, despite a firestorm of adverse publicity about the proposal. Fifteen months ago DHHS gave the privacy advocates the consent requirement they demanded, and has since had to live with a barrage of information from the health industry about the problems the requirement would cause to the delivery of patient care. Consequently, it seems unlikely that DHHS will flipflop yet again on this issue. If that proves true, beginning on April 14, 2003 the County will have somewhat greater leeway to use and disclose PHI prior to a first face-to-face encounter with an individual, for purposes of scheduling appointments and so forth, but as of that first encounter it seems that this change would affect the County very little, the documentation requirements for consents now being supplanted by documentation requirements for the Notice. However, in its proposal DHHS gives notice that it will "strictly enforce" the authorization requirements, as a way of making sure that patients retain the right to control their PHI in that context. This may affect portions of the County that are considering relying upon HIPAA authorizations to continue programs that are currently in effect (such as Passport); such an enforcement stance will make strict observance of the authorization rules even more important. The removal of the HIPAA consent requirement will probably also affect the preemption analysis of California law relating to consents and authorizations.

Hybrid Entity Rules. Although the hybrid entity provisions are buried in the "miscellaneous provisions" section at the back of the NPRM, the three proposed changes to the hybrid entity rules are of high importance to the County. First, DHHS proposes to allow those single legal entities that perform both covered and non-covered functions to *choose* whether to be a hybrid entity, or a single covered entity. A hybrid entity must designate its health care components; if no such components are designated, the entire entity would be a covered entity.

Second, DHHS proposes to simplify the definition of "health care component" so as to allow a hybrid entity flexibility in identifying the boundaries of those components. Under the proposed rule, health care components would be *required* to include the components of the covered entity that engage in covered functions (providing or paying for health care), and *may* also include any component that engages in business associate - type activities for those components (i.e., "any component that engages in activities that would make such component a business associate of a component that performs covered functions if the two components were separate legal entities"). In the current rules, inclusion of such business associate-type functions in the component is automatic.

If this proposed change becomes law, the hybrid entity may make a business decision as to which is better for the organization: making the business associate - type activity comply with HIPAA in its entirety, or obtaining an authorization from each patient before disclosing PHI to the business associate - type activity. For example, an in-house legal department that provides services to a health clinic operated by a hybrid entity could either become part of those clinic functions for HIPAA purposes by making all of its activities HIPAA compliant, or the hybrid entity could choose to obtain an authorization from each individual whose PHI is handled by the legal department. DHHS notes that disclosure outside the designated component (here, the clinic) would be the same as a disclosure outside of a covered entity, if the clinic and the legal department were separate legal entities, and so would be a violation unless permitted by the privacy rules. A business associate contract would suffice except that DHHS notes that "an entity cannot have a contract with itself," so that such a disclosure "would likely require individual authorization."

Third, DHHS proposes that *health care provider functions need not be included in the component unless they themselves engage in electronic HIPAA transactions*. As background on this issue, only those health care providers that engage in any of the nine electronic HIPAA transactions are "covered" health care providers that are subject to HIPAA. The question for counties and other hybrids has been whether the performance of electronic HIPAA transactions by *any* component within the hybrid covered entity serves to make *all* health care provider functions within the entity "covered" health care provider functions.

In its proposed changes DHHS acknowledges the ambiguity of the current rules on this point, and proposes to provide some flexibility for hybrid covered entities, as follows: if the health care provider function itself (or through an agent) engages in electronic HIPAA transactions, then that function *must* be part of a designated health care component. If it does not, then the hybrid covered entity *may choose* whether to include those health care provider services within a covered function component. DHHS frames this question as whether the health care provider services would be a covered entity if it were a separate legal entity; if it would (i.e., if it engages in electronic HIPAA transactions and would therefore be a covered health care provider) then it must be included in the health care component. Otherwise, its inclusion is optional.

Potential Impact on the County. If these proposals become law, the County will want to re-analyze its HIPAA compliance structure on several levels. First, it could choose to bring all of its operations into compliance with HIPAA rather than to designate numerous health care components. However, it is difficult to imagine that HIPAA implementation on a County-wide basis could be less complex than obtaining authorizations when necessary to disclose PHI among various County departments. Second, assuming that the County continues to follow the health care component approach, the County would have much greater leeway under the proposed rules for determining which functions should be in those components. For example, Adult Protective Services could continue to provide whatever health care provider functions it wishes, without being subject to HIPAA, because it does not itself engage in electronic HIPAA transactions. Similarly, the Probation Department could continue to both provide and contract with the Department of Mental Health to provide health care services to individuals under its jurisdiction, whether in Kirby or elsewhere, without being subject to HIPAA, assuming that it

does not engage in electronic HIPAA transactions (I believe but am not certain that the Probation Department does not do so).

Those portions of the County that provide health care and engage in electronic HIPAA transactions must be designated either as separate health care components, or as one large health care component. (Without any such designations, the County would be deemed to be a single covered entity with all of its operations subject to HIPAA.) For example, DMH and the Department of Health Services could either be combined into one covered function component or could remain separate components. A reason for combining them might be to enable sharing of PHI regarding mutual patients, for treatment, payment and operations purposes. If one component, they could share this PHI subject only to the minimum necessary requirements. If separate components, they would be allowed to share PHI with each other only as otherwise allowed by the privacy rules for separate covered entities. Under the current rules, this would be allowed either (a) when the disclosure is for treatment purposes, (b) with individual authorization or an intergovernmental HIPAA-compliant MOU (which is an option DHHS ignores when stating that an entity cannot have a business associate contract with itself), or (c) under any of the disclosures allowed by Section 164.512 (required by law; for administrative and judicial procedures; for abuse/neglect, etc.) as long as there is compliance with the rules for each of those types of disclosures. However, under another portion of the proposed rules, it would be possible to share PHI between DMH and DHHS for payment and certain health care operations purposes (see discussion below), and with this expansion of the rules, there may be no benefit to combining DHS and DMH into a single covered function component. This is just an example of how the County may wish to re-analyze its current covered function component structure under the more flexible proposed rules.

Third, a more difficult decision could be whether to combine various business associate-type functions with the covered components they serve, or instead to seek individual authorization for every disclosure of PHI to those business associate-type functions. These two choices which DHHS proposes could impact services provided by the legal department, the County auditor, and others to the covered function components. However, I believe that DHHS' statement that an entity cannot have a contract with itself is erroneous in the County context, considering the MOUs that are currently in use among County departments. *The County should consider submitting comments to DHHS on this point*, to obtain an acknowledgement that an intergovernmental MOU that is HIPAA compliant can serve in the County context as the equivalent of a business associate agreement, thereby authorizing disclosures of PHI from covered function components to those County departments that provide business associate-type services to the covered function components, and so avoiding the need for individual authorizations related to those disclosures.

Disclosures for payment and certain "health care operations" activities of other covered entities and non-covered health care providers. DHHS proposes relaxing the prohibition against disclosing PHI for the payment or operations purposes of another covered entity or non-covered health care provider. This prohibition has caused concern, for example, to ambulance service providers, billing services and health plans, all of whom have need of certain insurance, demographic or quality assurance information to perform their own functions, but have no access to that information except through a different covered entity. DHHS proposes to

allow disclosures for the payment activities of other covered entities and non-covered health care providers, as well as for some, but not all, health care operations activities (only those listed in the first two sections of the "health care operations" definition, as DHHS proposes revising it, and for the "purpose of fraud and abuse detection or compliance"). However, these operations-related disclosures would be allowed only to the extent that both the disclosing and the receiving entity have, or have had, a relationship with the individual.

Potential Impact on the County. To the extent that the County deals with private ambulance companies, outside billing and collection agencies, health plans and others who request an individual's PHI for their own operations purposes, this proposed change would allow the County to respond without obtaining the individual's authorization, as would be required under the current language of the rules. For example, it would allow the County to disclose demographic and other PHI to its contracting health care providers for payment and certain of their operations activities.

Oral Communications. In its Guidance of July 6, 2001 DHHS promised to clarify issues related to oral communications, and has undertaken to do so in the proposed rules. However, the clarifications do not bring much, if any, added comfort. Instead, they provide that "incidental" oral disclosures (ones that cannot reasonably be prevented, are limited in nature, and that occur as a by-product of an otherwise permitted use or disclosure) are permitted, *but only to the extent* that the covered entity has "applied reasonable safeguards" and has implemented the minimum necessary standard. The clarifications therefore impose a number of requirements that must be complied with, else the "incidental" oral disclosure (to be distinguished from "inadvertent" or "mistaken," which are *not* protected by this proposed change) will be a civil and criminal violation of HIPAA. The clarifications therefore will require greater attention to the "reasonable safeguards" that could be applied to physical settings where PHI is spoken aloud, and apparently also to the application of "minimum necessary" rules in those settings.

Potential Impact on the County. While the County will be impacted along with all other covered entities by the issues raised above, there do not seem to be unique County issues under these proposed changes.

Minimum Necessary. DHHS did not propose anything other than minor clarifications to this rule, but noted that it intends to "issue further guidance to clarify issues causing confusion and concern in the industry, as well as provide additional technical assistance materials to help" implement the provisions. There is no indication as to what this assistance might address, or when it will be forthcoming. Beyond this, the DHHS discussion does include a noteworthy paragraph that ties the minimum necessary rule to physical and technical security "adjustments" that may need to be made in order to implement the minimum necessary rule. This discussion implies that failure to adequately implement physical or technical security under HIPAA's security rules will also be a violation of the minimum necessary rule, and vice versa, and so has implications for enforcement and civil and criminal penalties.

Potential Impact on the County. While the County will be impacted along with all other covered entities by the issues raised above, there do not seem to be unique County issues under these proposed changes. However, the County may wish to move its "minimum

necessary" compliance tasks down towards the bottom of its implementation task list, pending additional rulemaking by DHHS.

Business Associates. DHHS is proposing a limited delay in the business associate contract requirement. The delay would apply only to contracts in existence prior to April 14, 2003, and would be effective only until either (1) those contracts were renewed (other than by an "evergreen" renewal provision) or modified, or (2) April 14, 2004, whichever first occurs. However, notwithstanding the delay, to the extent that the business associate holds part of the designated record for an individual, the covered entity would be required to involve the business associate in any requests for access, amendment or accounting related to that individual, and to cause the business associate to make their books and records available to the Secretary of DHHS. Without a contractual agreement that includes the HIPAA business associate provisions regarding these activities, it may be difficult to get the business associate to provide the information necessary for an accounting, or to promptly comply with access, amendment and DHHS disclosure requests. Consequently, the value of this delay might be less than anticipated, especially for those contracts where the business associate holds part of the designated record set.

Potential Impact on the County. This potential for delay in business associate contract compliance would give the County the option to move those activities later in its HIPAA implementation schedule and free up resources needed for more urgent implementation tasks. However, for those contracts that involve part of a designated record set, the County may wish to put the business associate provisions in place by April 14, 2003 in order to avoid the potential problems described above. County attorneys will likely find in the sample language proposed by DHHS to be interesting, but may decide to keep the County's current model form in the same or substantially the same format.

Marketing. The rules on use of PHI for communications with patients that involve "marketing" would become simpler but more restrictive under the DHHS proposal. The "disclose and opt out" provisions for "marketing" health-related products and services to patients would disappear, and instead, the rule would require the patient's prior authorization for most of these communications -- in essence, an "opt in" approach. Still in place would be the rule that any expected "direct or indirect remuneration" from a third party for these communications must be disclosed in the authorization form (with an exception for face-to-face "marketing" communications, for which an authorization is not required). While the very broad definition of "marketing" would remain essentially the same, there would be new exceptions, or carve-outs, from that definition, for communications (1) describing network participants and available benefits; (2) for the individual's treatment; and (3) for case management or care coordination and treatment-related recommendations. In addition, even though they constitute "marketing," a prior authorization would not be required for (a) face-to-face communications by a covered entity with an individual (even if they involve direct or indirect remuneration); or (b) promotional gifts (pens and other trinkets) of nominal value provided by the covered entity. So the rules would still be complex, but less so, with the net effect of requiring authorizations for more types of these patient-focused communications that fall within the broad "marketing" definition.

Potential Impact on the County. Along with other covered entities, the County should discuss with its health care providers and others who communicate with patients this new definition of "marketing," to compare it with the types of communications that are used with patients and to determine whether and when authorizations will be required.

Parents and Minors. In the Guidance of July 6, 2001, DHHS promised to revisit the highly political issue of the balance of power over PHI between parents and their unemancipated minor children. In the current rules DHHS defers to State law by declaring that, with certain exceptions, a child with the power to consent to treatment under State law is also given the right to exercise the privacy rights afforded to individuals under the HIPAA privacy rules, related to that specific treatment. In the comments to its new proposal, DHHS asserts that its approach remains the same and that it is proposing changes "to better implement that approach;" however, the changes proposed significantly change the balance of power between parents and their minor children, compared to that balance in the current rules.

The net results of the proposed changes are as follows:

1. *Disclosures to Parents.* Minors would have the right to keep their PHI from being disclosed to a parent only when the State prohibits such disclosures. Whenever "applicable State or other law, including applicable case law" can be found that would "permit" disclosure to a parent (and in its comments DHHS inconsistently indicates that "permit" means either "is silent" or "expressly permits"), then a provider may disclose the minor's PHI to the parent, even when the minor holds the sole legal right to consent to the underlying treatment.
2. *Exercise of HIPAA Access Rights by Parents.* Although a minor would have limited rights to control *disclosure* under the proposed rules, the minor apparently would have no right under the proposed rules to prevent the parent from exercising the right of *access* to the minor's PHI, using HIPAA's access provisions. Even when the parent is not technically the minor's personal representative, the proposed changes would permit a provider to allow the parent to exercise the right of access to the minor's PHI, again regardless of the minor's right to solely consent to the treatment at issue.

The battle over minors' and parents' rights in a minor's PHI has been and continues to be fierce. DHHS's assertions that its proposed changes represent no shift in the balance described in the current rules can be best understood in that light.

Potential Impact on the County. Because the County may frequently find itself in the middle between parents and minors on the issue of minors' PHI privacy rights, and because this is a highly political issue that could result in adverse publicity for the County even under circumstances where everything is done right, once these rules are finalized the County should pay particular attention to its policy development and provider training on these issues.

Uses and Disclosures for Research Purposes (including Research-related Authorizations). After a lengthy discussion of the ambiguities, inconsistencies and confusion caused by the interplay between HIPAA's research-related requirements and the Common Rule,

DHHS is proposing to consolidate the findings required of IRBs or privacy boards before those entities may approve the use of PHI without an individual's authorization for research purposes. What would remain are three required findings: (1) that the use of PHI involves no more than minimal risk to the privacy of individuals, (2) that the research could not practicably be conducted without the waiver or alteration of an individual's authorization; and (3) that the research could not practicably be conducted without access to and use of the PHI.

Under the first finding DHHS would fold several elements that are currently required as stand-alone findings: whether there is an adequate plan to (a) protect identifiers from improper use and disclosure and (b) destroy the identifiers at the earliest opportunity (unless there is a health or research justification for retaining them, or doing so is required by law); and whether there are adequate assurances against reuses or redisclosures that are not either required by law, for authorized oversight of the research project, or for other research permitted by the privacy rules.

As discussed in detail below, DHHS also proposes to collapse the research authorization requirements into a single universal authorization form to be used in all cases where an authorization is required, whether inside or outside the research context. DHHS also proposes to modify its prohibitions against "compound authorizations" so that one authorization form would suffice to grant use and disclosure of an individual's pre-research PHI (history and physical, etc.) along with the PHI that will be generated during the course of the clinical trial. Finally, when the universal authorization form is used for research related to treatment, DHHS proposes specific language that would be appropriate for the research context, as follows: for an expiration date or event, the statement, both "end of the research study" or similar language, or "none" would suffice, the latter being intended to allow the use of PHI in the limited context of a research database or repository. DHHS notes that the use of "none" as a termination date or event will *not* serve to authorize future research on that database or repository; for that purpose, "end of the research study" or similar language would be required.

DHHS also proposes relaxing the research-related transition provisions, so that all research studies (whether or not they involve treatment) that have, prior to the compliance date, either (1) any type of express legal permission to use or disclose PHI for the research project; (2) informed consent; or (3) an IRB waiver, may continue to use and disclose PHI after the compliance date in accordance with those documents.

Potential Impact on the County. To the extent that the County engages in medical research, or allows others to do so in County facilities or using the PHI of County patients, the simplification of the research-related waiver and authorization requirements will make these activities less complicated to implement. However, DHHS has asked for comments regarding the definition of de-identified information as used in the research context (see discussion below), and regarding issues that are raised when an individual revokes an authorization related to research. Future guidance from DHHS in these areas can be expected.

Authorization Requirements. Based on numerous complaints that the four sets of authorization requirements in the current rules are "too complex and confusing," DHHS proposes to simplify those requirements down to one form suitable for every authorization.

Although it does not provide the actual form, DHHS does provide the language for the provisions in the form, all but one of which are either verbatim or somewhat modified from the authorization elements in the current rules. For the one entirely new element, the form must state the consequences to the individual of a refusal to sign the authorization when the covered entity can condition treatment, enrollment in a health plan, or eligibility for benefits on failure to obtain the authorization. Under the proposal, disclosure of direct or indirect remuneration related to the authorization would be required only when the disclosure is for "marketing" purposes, as discussed above.

DHHS also provides acceptable language for certain elements in the form. For example, when an individual initiates the authorization, the description for the "purpose" element of the form may simply read, "at the request of the individual." Other phrases deemed acceptable by DHHS for research-related authorizations is described above.

Finally, DHHS proposes to exempt uses and disclosures based on an authorization from the minimum necessary rules; clarifies that the use or disclosure of psychotherapy notes for the health care operations of another entity requires an authorization; and makes other amendments to the authorization provisions to make them consistent with other proposed changes in the rules, such as the elimination of the consent requirement.

Potential Impact on the County. Along with other covered entities, the County stands to benefit from the simplification of the authorization rules. The authorization form drafted for the Passport program should be revised accordingly, after these proposed rules are issued in their final form; however, it should be noted that except for research-related authorizations, the prohibition against "compound authorizations" remains in effect. In fact, that prohibition is arguably made more plain because the research exception mentions combining the authorization with "consent" and "any other type of written permission," thereby implying that outside the research context, these combinations would constitute an impermissible "compound authorization."

De-identification. DHHS clarified in its comments that a "re-identification code" assigned by a covered entity to de-identified information is not considered to be PHI, as long as it is not derived from or related to information about the subject of the information, and is not otherwise capable of being translated so as to identify the individual. Otherwise, DHHS is not currently proposing changes to the de-identification provisions. However, it is soliciting comments on an alternative that would allow limited use of data sets that do not contain "facially identifiable information" but in which certain identifiers would remain. This is largely in response to the concerns of researchers and of state hospital associations who gather patient information from constituent hospitals in order to conduct and disseminate analyses that are used by those hospitals in making decisions about quality and efficiency improvements and community health care needs.

Potential Impact on the County. To the extent that the County would be interested in being able to use the limited data sets being considered by DHHS, the County may wish to submit supportive comments during the comment period, which ends April 26th.

Miscellaneous Provisions. In addition to a number of technical corrections, DHHS proposes to: more clearly allow transfer of PHI to another covered entity upon a sale, transfer, merger or consolidation; allow disclosures of enrollment/disenrollment information by group health plans to plan sponsors without the amendment of plan documents; eliminate disclosures based on authorizations from inclusion in accountings of disclosures; clarify permission to make required or authorized reports to the FDA and others subject to its jurisdiction; and except "employment records" from the definition of PHI, so that a covered entity that is also an employer with PHI in its employment records will not be required to declare itself a hybrid entity.

I am available to discuss these issues with you further at your convenience.